FILED WITH LRC TIME: 2 pm JUL 2 0 2012

> Donna Little REGULATIONS COMPILER

- 1 General Government Cabinet
- 2 Kentucky Board of Medical Licensure
- 3 (New Administrative Regulation)
- 4 201 KAR 9:230. Required Registration in the KASPER System; Legal
- 5 Requirements for Prescribing Controlled Substances in the Commonwealth of
- 6 Kentucky; Enforcement.
- 7 RELATES TO: KRS 311.530-311.620, 311.990, 218A.202
- 8 STATUTORY AUTHORITY: KRS 311.565(1)(a)
- 9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a)
- 10 authorizes the board to promulgate administrative regulations to regulate the
- 11 conduct of its licenses. KRS 311.595(9) and (12) and 311.597 authorize
- 12 disciplinary action against licensees for specified offenses. This administrative
- 13 regulation establishes required registration in the KASPER system; legal
- 14 requirements for prescribing controlled substances in the Commonwealth of
- 15 Kentucky; enforcement.
- Section 1. (1) Effective July 20, 2012, every licensee who holds a valid Drug
- 17 Enforcement Administration (DEA) permit to prescribe or dispense controlled
- 18 substances to humans in the Commonwealth of Kentucky must be registered
- 19 with the Cabinet for Health and Family Services to use the KASPER system;
- 20 (2) Any licensee who obtains a DEA permit to prescribe or dispense
- 21 controlled substances to humans in the Commonwealth of Kentucky following

- July 20, 2012 shall register, within three (3) working days of the date of issuance
- 2 of the DEA permit, with the Cabinet for Health and Family Services to use the
- 3 KASPER system;
- 4 (3) Every licensee who holds a valid DEA permit to prescribe or dispense
- 5 controlled substances to humans in the Commonwealth of Kentucky shall
- 6 maintain registration with the Cabinet for Health and Family Services to use the
- 7 KASPER system continuously during their licensure within the Commonwealth of
- 8 Kentucky;
- 9 (4) Failure of a licensee to register with the Cabinet for Health and Family
- 10 Services to use the KASPER system within the time designated or to maintain
- such registration continuously during their licensure, as required by Sections (1)-
- 12 (3), above, shall constitute violations of KRS 311.595(9) and (12) and shall
- provide a basis for disciplinary action against their Kentucky licenses pursuant to
- 14 KRS 311.595.
- 15 Section 2. (1) In order to lawfully prescribe or dispense controlled
- substances within the Commonwealth of Kentucky, a licensee must hold a valid
- 17 DEA permit to do so and must be registered with the Cabinet for Health and
- 18 Family Services to use the KASPER system;
- 19 (2) Failure to be registered with the Cabinet for Health and Family Services to
- 20 use the KASPER system at any time while the licensee holds a valid DEA permit
- 21 to prescribe or dispense controlled substances to humans within the
- 22 Commonwealth of Kentucky shall constitute a violation of KRS 311.595(9) and

- 1 (12) which constitutes an immediate danger to the public health, safety, or welfare, for the purposes of KRS 311.592 and 13B.125.
- 3 (3) If the Board receives documentation from the Cabinet for Health and
- 4 Family Services that a licensee holds a valid DEA permit to prescribe or dispense
- 5 controlled substances to humans within the Commonwealth of Kentucky, but is
- 6 not currently registered with the Cabinet to use the KASPER system, the Board
- 7 shall:
- 8 (a) immediately send written notice, by certified mail, to the physician that the
- 9 physician must register with the Cabinet for Health and Family Services to use
- 10 the KASPER system within seven (7) days of receipt of the written notice;
- (b) confirm with the Cabinet for Health and Family Services that the physician
- registered with the Cabinet to use the KASPER system; and,
- 13 (c) if the physician failed to register with the Cabinet for Health and Family
- 14 Services to use the KASPER system within the seven (7) days following receipt
- of the written notice, the appropriate Inquiry Panel or its Chair shall promptly
- issue an emergency order restricting that licensee from prescribing or dispensing
- 17 controlled substances within the Commonwealth of Kentucky until such time as
- 18 the licensee has registered with the Cabinet to use the KASPER system;
- 19 (4) An emergency order restricting a licensee from prescribing or dispensing
- 20 controlled substances within the Commonwealth of Kentucky issued pursuant to
- 21 subsection (3) above shall remain valid and in effect until the Board has received
- 22 written verification from the Cabinet that the licensee has registered with the
- 23 Cabinet to use the KASPER system. Upon receipt of such written verification,

- 1 the Panel or its Chair will immediately issue an order terminating the emergency
- 2 order issued pursuant to this section;
- 3 (5) If a licensee who is affected by an emergency order issued pursuant to
- 4 this section requests an emergency hearing pursuant to KRS 13B.125(3), the
- 5 hearing officer conducting the emergency hearing shall affirm the emergency
- 6 order of restriction if presented with a written notification on Cabinet letterhead
- 7 stating that the affected licensee holds a valid DEA permit but is not registered
- 8 with the Cabinet to use the KASPER system.
- 9 Section 3. If a licensee should prescribe or dispense controlled substances
- within the Commonwealth of Kentucky during any period when the licensee is not
- 11 registered with the Cabinet to use the KASPER system, each instance of
- 12 prescribing or dispensing shall constitute a separate violation of KRS
- 13 311.595(12) and (9), as illustrated by KRS 311.597(1)(b) and will serve as the
- basis for disciplinary sanctions pursuant to KRS Chapter 311.595.

Adopted:

7/20/2012 DATE

PRESTON P. NUNNELLEY, M.D., PRESIDENT KENTUCKY BOARD OF MEDICAL LICENSURE PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on September 26, 2012 at 10:00 a.m. at the offices of the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by September 19, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until October 1, 2012. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: C. Lloyd Vest II, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7150, fax (502) 429-7118.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: C. Lloyd Vest II, General Counsel, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222: (502) 429-7150.

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes the requirements for required registration in the KASPER system and provides for enforcement by the Board.
- (b) The necessity of this administrative regulation: It is necessary to establish the requirements for registration in the KASPER system and to provide for enforcement by the Board.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation acts specifically to establish the requirements for required registration in the KASPER system and to provide for enforcement by the Board.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation acts specifically to establish requirements for registration in the KASPER system and provides for enforcement by the Board.
- (2) If this is an amendment to an existing regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation; Not Applicable.
 - (b) The necessity of the amendment to this administrative regulation; Not Applicable.
 - (c) How the amendment conforms to the content of the authorizing statutes; Not Applicable.
 - (d) How the amendment will assist in the effective administration of the statutes. Not Applicable.
- (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This is a new administrative regulation that will affect all physicians licensed in the Commonwealth of Kentucky that hold a valid DEA permit to prescribe controlled substances.
- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Each physician that holds a valid DEA permit to prescribe or dispense controlled substances in the Commonwealth of Kentucky must

- register with the Cabinet for Health and Family Services to use the KASPER system.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The Kentucky Board of Medical Licensure will not charge a fee for compliance with regulation.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Physicians will be able to monitor patients who are prescribed controlled substances in the Commonwealth of Kentucky.
- (5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: None
 - (b) On a continuing basis: None
- (6) What is the source of funding to be used for the implementation and enforcement of this administration regulation: None.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase of fees or funding will be necessary.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish any fees nor does it directly or indirectly increase any fees.
- (9) TIERING: Is tiering applied? (Explain why or why not)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 201 KAR 9:030 Contact Person: C. Lloyd Vest II Phone number: 502/429-7150

- (1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? None
- (2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311.565(1)(a), 218A.202
- (3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None
- (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None
- (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None
 - (c) How much will it cost to administer this program for the first year? None
- (d) How much will it cost to administer this program for subsequent years? None

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: